K963293

510(k) Summary

Augustine Medical Wound Care System

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General Information

Classification	Unclassified
Trade Name	Augustine Medical Wound Care System
Submitter	Augustine Medical, Inc. 10993 West 70th Street Eden Prairie, MN 55344 (612) 947-1200
Contact	Scott D. Augustine, MD CEO

Predicate Devices

The Augustine Medical Wound Care System is substantially equivalent in safety and effectiveness in its intended use to these predicate devices:

ClearSite Wound Dressing
K914207 & K920677
Manufactured by NDM Corporation, 3040 E. River Road, Dayton, Ohio 45439-1436, (800) 783-1767

Lyofoam Wound Dressing
K860085
Manufactured by Acme United Corporation, Medical Division, 75 Kings Highway Cutoff, Fairfield, CT 06430-5340, (800) 243-9852

Seabrook MicroTemp Pump and Pads
K843146
Manufactured by Seabrook, Inc. 4043 McMann Road, Cincinnati, OH 45245, (800) 477-7757

Device Description

The wound care system is comprised of a power supply/battery charger, heater control unit, heater card, and a sterile dressing/bandage called a Wound Cover which supports the heater card and holds it away from the wound and skin.

The Wound Cover is a disposable, single-use, sterile, non wound-contact dressing. The Wound Cover may be used either as a stand-alone wound dressing or as part of the Augustine Medical Wound Care System. The Wound Cover incorporates a clear or opaque window. The clear window allows the caregiver to view and assess the tissue. The Wound Cover surrounds and protects the wound, absorbs wound exudate and allows active warming of the periwound area by the application of radiant heat.

The warming components of the system include a thin heater card, a control unit, and a power supply/battery charger. The system operates on standard wall outlet electricity or the self-contained batteries. The heater card is sized appropriately to the Wound Cover and attaches easily over the clear window of the Wound Cover. The heater card does not contact the wound and is intended for single patient use. The control unit incorporates temperature safety limits.

Intended Use

The Wound Care System is intended to be used for the local management of wounds by maintaining moisture and body temperature in the wound bed and is indicated for partial and full thickness wounds, such as, Stage I through IV venous, arterial, diabetic, and pressure ulcers.

Testing

Biocompatibility testing was performed on the materials used in the construction of the sterile dressing. All materials passed biocompatibility testing and are suitable for this application.

Physical testing of the product included: dimensional inspection, functional performance, electrical safety, electromagnetic compatibility, pressure switch activation, overtemperature safety shut-off, and performance under clinical conditions. All testing of the product yielded acceptable results.

Summary of Substantial Equivalence

The Augustine Wound Care System components are constructed of the same or substantially equivalent materials as the predicate products. The sizes and configurations available along with the packaging and sterilization methods are also equivalent.

The clinical indications for use are substantially equivalent to the predicate devices as well.

Therefore, because of the similarity of materials to other wound treatment products, the test results, and the similar indications for use of the predicate devices, Augustine Medical believes these products do not raise any new safety or effectiveness issues.